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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Naoya KOJIMA et al.

Group Art Unit: 1615

Appln. No. : 10/598,916

Examiner: Unassigned

(U.S. National Stage Entry of PCT/JP05/005446)

I.A. Filed : March 17, 2005

Confirmation No.: 2020

For : DRUG DELIVERY SYSTEM USING AN IMMUNE RESPONSE SYSTEM

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop Amendment  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicants hereby bring the following information to the attention of the Examiner, which includes information cited and discussed in the International Search Report, the Written Opinion and the International Preliminary Report on Patentability issued in connection with International Application No. PCT/JP05/005446. Copies of the International Search Report (in English and Japanese), the Written Opinion (in Japanese) and the International Preliminary Report on Patentability (in Japanese) were enclosed with the papers when entering the National Stage on September 14, 2006. We enclose herewith copies of the Written Opinion and the International Preliminary Report on Patentability in English. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein.

- (1) JP 62-294432 A, December 21, 1987, accompanied by an English language abstract of family member EP 0241376;
- (2) WO 95/11704 A1, May 4, 1995;
- (3) U.S. Patent No. 5,759,572 (SUGIMOTO et al.), issued June 2, 1998; Applicants note that this document is identified on esp@cenet as a U.S. family member of document (2);
- (4) JP 07-126185 A, May 16, 1995, accompanied by an English language abstract thereof; Applicants note that this document has issued JP 2828391 B2 on September 18, 1998, which is identified on esp@cenet as a family member of documents (2) and (3); JP 2828391 B2 is cited and discussed in the present application, beginning on page 5 of the specification;
- (5) FUJIWARA, H. et al., "Fukumaku Limpa Soshiki no Tokusei ni Motozuku Gan Bisho Fukumaku Ten'I ni Taisuru Hyoteki Idenshi Chiryo", Japanese Journal of Cancer and Chemotherapy, 2002, Vol. 29, No. 12, pp. 2322-2324; and
- (6) SHIMOMA et al., "Fukumaku Ten'i Keisei ni Okeru Taimo Nyuhan no Igi", Oncologis, 1991, Vol. 24, No. 3, pp. 80-85.

Furthermore, Applicants direct the attention of the Examiner to the following documents:

- (7) JP 54-113417 A, September 5, 1979;
- (8) U.S. Patent No. 4,356,167 (KELLY), issued October 26, 1982; Applicants note that this document is identified on esp@cenet as a U.S. family member of document (7);
- (9) U.S. Patent Application Publication 2006/0193906 A1 (YAMAZAKI et al.), published August 31, 2006;

- (10) WO 2006/025411 A1, March 9, 2006;
- (11) EP 1 447 081 A1, August 18, 2004; and
- (12) KR 2005-0081889 A, August 19, 2005, accompanied by a machine English language translation thereof.

Copies of the above-noted documents with the exception of documents (3), (5), (6), (8) and (9), are enclosed together with a duly completed Form PTO-1449 listing all the documents (1)-(12). The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that copies of documents (5) and (6) should have been provided to the office by the international Office in connection with International Application No. PCT/JP05/005446. However, if additional copies are needed, the Examiner is respectfully requested to contact the undersigned.

Further to 37 C.F.R. §1.98 (a)(2)(ii), copies of the U.S. patents and the U.S. patent application cited above as documents (3), (8) and (9) are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if an Office Action on the merits has issued and is crossing this statement in the mail, the undersigned hereby authorizes the Commissioner to charge any fee necessary for

Attorney Docket No. P30703

Application No. 10/598,916

the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

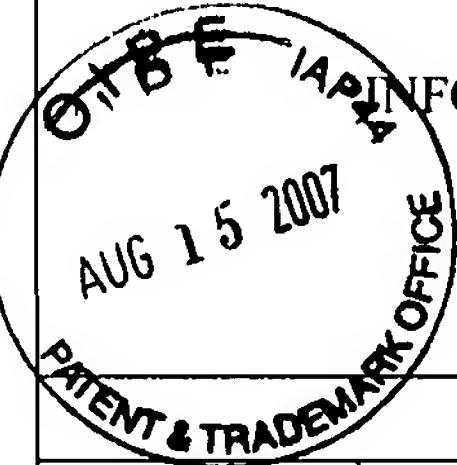
Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,  
Naoya KOJIMA et al.

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FORM PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. P30703	Application No. 10/598,916		
 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				Applicant Naoya KOJIMA et al.			
				Filing Date I.A. Filed March 17, 2005	Group 1615		
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5 7 5 9 5 7 2	06/02/98	SUGIMOTO et al.			
		4 3 5 6 1 6 7	10/26/82	KELLY			
	2006 /	0 1 9 3 9 0 6	08/31/06	YAMAZAKI et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO
	62	- 2 9 4 4 3 2	12/21/87	JAPAN			
	9	5 / 1 1 7 0 4	05/04/95	W.I.P.O.			
	7	- 1 2 6 1 8 5	05/16/95	JAPAN			
	54	- 1 1 3 4 1 7	09/05/79	JAPAN			
	2006	/ 0 2 5 4 1 1	03/09/06	W.I.P.O.			
		1 4 4 7 0 8 1	08/18/04	E.P.O.			
	2005	0 0 8 1 8 8 9	08/19/05	REPUBLIC OF KOREA			X
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
		English Language Abstract of EP 0 241 376.					
		English Language Abstract of JP 7-126185.					
		FUJIWARA, H. et al., "Fukumaku Limpa Soshiki no Tokusei ni Motozuku Gan Bisho Fukumaku Ten'I ni Taisuru Hyoteki Idenshi Chiryo", Japanese Journal of Cancer and Chemotherapy, 2002, Vol. 29, No. 12, pp. 2322-2324.					
		SHIMOMA et al., "Fukumaku Ten'i Keisei ni Okeru Taimo Nyuhan no Igi", Oncologis, 1991, Vol. 24, No. 3, pp. 80-85.					
EXAMINER				DATE CONSIDERED			
<small>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>							